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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,098	12/28/2001	Geoffrey P. Symonds	J&J 2084	1700

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EXAMINER

SCHULTZ, JAMES

ART UNIT PAPER NUMBER

1635

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

### Application No.

10/035,098

### Applicant(s)

SYMONDS ET AL.

### Examiner

J. Douglas Schultz

### Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-67 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The numbering of claims is not in accordance with 37 CFR 1.126, because claim 61 has been listed twice. The second occurrence of originally filed claim 61 has been re-numbered as claim 62, and the following claims have been renumbered accordingly.

### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 2, 3, 5-9, 12, 13, 16, 18, 20-33, 61, 62, and 64-66, are drawn to a double stranded RNA molecule comprising a third strand of RNA that comprises a ribozyme and a target sequence present in the third strand which is cleaved out by the ribozyme, classified in class 536, subclass 24.5
  - II. Claims 2, 3, 5-11, 21-33, 61, 62, and 64-66 are drawn to a double stranded RNA comprising a third region comprising RNA encoding the protein Tat, classified in class 536, subclass 24.5.
  - III. Claims 2, 3, 5-9, 17, 19-33, 61, 62, and 64-66 are drawn to a double stranded RNA wherein the second strand comprises a polyadenylation signal and a ribozyme capable of cleaving said polyadenylation signal, classified in class 536, subclass 24.5.
  - IV. Claims 2, 3, 5-9, 14, 17, 21-33, 61, 62, and 64-66 are drawn to a double stranded RNA that comprises a third strand comprising an intron or linker, classified in class 536, subclass 24.5.

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- V. Claims 34-58, 60, and 63, drawn to methods of inhibiting protein expression using a double stranded RNA comprising a first and second portion which comprises a polyadenylation signal and a hammerhead ribozyme, classified in class 514, subclass 44.
- VI. Claims 59 and 67, drawn to a method of identifying the function of a gene in a cell using a double stranded RNA molecule, classified in class 435, subclass 6.

Claims 1, 4, and 15 link(s) the inventions of Groups I-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 4, and 15 in regards to Groups I-VI, and claim 19 in regards to Groups I, III, V and VI. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions of Groups I-IV are considered to be unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they

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have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each Group is drawn to a compound comprising a unique nucleotide sequence. Group I requires a sequence that is targeted by a ribozyme, Group II requires an oligo containing a Tat sequence, Group III requires a polyadenylation signal, and Group IV requires a sequence containing an intron. None of these Groups are disclosed as working together, and furthermore, the unique sequence of each Group is structurally and functionally independent and distinct from that of the other Groups. Because the mode of operation and function of a nucleic acid oligo is dependent solely upon its sequence, the sequences of Groups I-IV have different modes of operation, different functions, and different effects from one another. Furthermore, a search of more than one (1) Group presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed compounds. In view of the foregoing, one (1) Group comprising a unique sequence is considered to be a reasonable number of sequences for examination.

The products of Groups I-IV are related the methods of Groups V and VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case methods of inhibiting gene expression of Group V or testing for gene function of Group VI can be accomplished using single stranded antisense nucleic acid inhibitors, which are materially different products than

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those claimed, but will nevertheless achieve the claimed function of inhibiting expression of a protein.

The methods of Groups V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together, and have different effects, because the method of Group VI requires determining the effect of gene inhibition on the cell, which is not required of Group V.

Because these inventions are distinct for the reasons given above and the search required for any of the above Group is not required for any other Group, a search and examination of each of these Groups in a single application represents an undue burden on the Office because the searches are divergent and not co-extensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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